# Participant Information Sheet

## DiReCT – Improving Recruitment into Clinical Trials

### What is the purpose of the study?

The DiReCT study is investigating the possibility of recruiting a group of people with common mental health problems, such as depression and anxiety, to take part in health research.

One of the main reasons for doing this is because most people with common mental health problems do not get offered the chance to take part in research. At the moment, only 10% of people with depression take part in research to test new treatments. If more people take part in health research there will be a greater chance of finding better treatments and improving health services for people with common mental health problems.



In the DiReCT study, we want to find out whether it would be possible to improve this situation in the future and are interested in finding out the following:

- How many people with common mental health problems attending an assessment at the Depression and Anxiety Service of Devon Partnership NHS Trust would agree to take part in research designed to improve treatments for common mental health problems?

- How many of these people would then agree to being selected at random to receive new treatments as part of clinical trials, if and when these treatments become available?

### Why have I been invited?

You have been invited because you have been referred to the Depression and Anxiety Service of Devon Partnership NHS Trust and are over 18 years of age.

This information sheet is for you to keep, if you decide to take part, one of our research team will go through the information sheet with you and answer any questions you have.

## What is the procedure that is being tested?

We are testing a new method for recruiting participants into health research. The procedure we are testing is as follows:

1. New patients to the Depression & Anxiety Service will be asked by a member of their health team if they wish to take part in the DiReCT study.

2. This member of your health team will explain the study and will ask you if you consent to being interviewed by an independent researcher. You will also be asked if you agree to your medical records being looked at by these researchers (to help with health research) and also if you are happy to be contacted again in the future to be offered the chance to take part in other research studies.

3. The member of your health team will ask you if you consent to being selected at random to be offered new treatments as part of clinical trials if and when these treatments become available in the future.

We would like to know whether you would find these requests acceptable and we will test this by asking you to sign a consent form.

At this stage we are only investigating the possibility of setting up a new system of recruitment. We are interested only in what we call the 'feasibility' of this system. So in this stage of the research we will not actually look at your records nor will we be able to offer you the chance to take part in any treatments. We just want to know if this system would work in the future.



## Do I have to take part?

No. It is entirely up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. You will still be free to withdraw at any time and without giving a reason. A decision to withdraw or not to take part will not affect the care you receive in any way.

## What will happen to me if I take part?

If you decide you would like to take part, a researcher will contact you by telephone. We will wait at least 48 hours after you have signed the consent form before calling you. Since this study is only a test of our procedures, our telephone call to you will be short and just to confirm that you understand what the study is about and check that you would find this procedure acceptable. Your involvement in the study would end after this telephone call.

## What information do you need from me?

If you agree to take part in the study, the only thing we need from you is your signed consent form and your contact details so that we can contact you to confirm that you understand what the study is about and would be happy to take part.

## Will I have to do anything differently?

No, there are no restrictions in your lifestyle from taking part in this research. You should continue to follow the advice of your GP.

## Are there any side effects, disadvantages and risks of taking part?

We are not aware of any side effects, disadvantages or risks to you of taking part in this research.

## What are the possible benefits of taking part?

Taking part in the study may encourage you to know that you are contributing to the development of a better system for recruiting people into health research that may, in turn, help other people suffering from your condition.

## What happens when the research study stops?

Throughout the study and afterwards, your GP and clinical team will continue to treat you as they feel is best for you and with your agreement.

## Will my taking part in this study be kept confidential?



All information collected about you during the course of the study will be kept strictly confidential. Your contact records will be kept on a secure database at the University of Exeter and we will adhere to data protection laws by following a confidentiality protocol.

Any personally identifiable written data will be shredded and destroyed within three months of the study completion using confidential waste disposal systems at the University.

Please note that if at any time during an interview with a researcher from the DiReCT team, we become concerned for your personal safety or that of others, the researcher will follow a standard procedure to ensure that you and/or their dependents remain safe. If we are very concerned about safety we will be obliged to inform your GP, clinical service and if necessary the emergency services. This is the only instance where we will have to breach your confidentiality.

## What will happen to the results of the research study?

We will produce an internal report from the results of the study and will inform our funder, the National Institute for Health Research (NIHR) of the results. We will also publish a summary of the findings on our website: www.exeter.ac.uk/mooddisorders/direct and may publish an article in an academic journal. You will not be personally identified in any publications from this study.

We will use the results of this study to decide whether to set up a fully functioning recruitment system for people with common mental health problems in the future.

## What if something goes wrong or I have a complaint?

We do not expect any harm coming to you from being in this study. However, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you through the Patient Advice and Liaison Service (PALS) on 0800 0730741.

## Who is organising and funding the research?

The National Institute of Health Research has funded this research study, which is supported by the Department of Health. It is not a commercially funded industry trial; this means that neither the member of your health team who invited you to express your interest nor the research team will receive any extra money for conducting this study. The study is sponsored by the University of Exeter.

## Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights well-being and dignity. This study has been reviewed by the NRES Committee East Midlands – Nottingham 1 REC Proportionate Review Sub-Committee. This study has also been reviewed by the National Institute of Health Research and an independent researcher from the University of Sheffield.

## Further Information – Next Steps



Please take time to read the consent form and indicate whether you consent to each part of the study by marking your initials in the box next to your answer. Please sign and date the form and hand it to your health worker from the Depression & Anxiety Service.

If you need further information to help you decide, please contact Professor David Richards at the address below.

*Thank you for reading this and for considering taking part in this study.*

## Contact for Further Information

If you need further information about this study please contact:

David A Richards
Professor of Mental Health Services Research
Sir Henry Wellcome Building for Mood Disorders Research
College of Life & Environmental Sciences
University of Exeter
The Queen's Drive
Exeter
EX4 4QQ

Email: d.a.richards@exeter.ac.uk

**Telephone: 01392 724615**

www.exeter.ac.uk/mooddisorders/direct

DiReCT
Recruitment into Clinical Trials

## Improving Recruitment into Clinical Trials

# CONSENT FORM

| **Site Details:** Depression and Anxiety Service (DAS), Devon | **Please initial box** |
|---|---|
| 1. I confirm that I have read and understand the DiReCT Information Sheet (Date: ) and have had the opportunity to ask questions. | |
| 2. I consent to be contacted by researchers to be interviewed about my health and have information about my health collected. | |
| 3. I consent to researchers contacting me to offer treatments being tested as part of health research. I understand that I will be selected at random for any treatments offered to me. I understand that I may not be selected to receive any treatments at all. | |
| 4. I consent for my medical records held by the Depression & Anxiety Service to be looked at by researchers to help with health research. | |
| 5. I understand that my participation in all of the above is voluntary. In particular, I understand that I do not need to accept any treatments if they are offered to me. I understand I am free to withdraw at any time, without giving any reason, and that this will not affect my medical care or legal rights. | |



**For Participant:** When you have initialled the boxes above, please sign and date below.

| Name of Participant: | Date: | Signature of Participant: |
|---|---|---|
| _____ | _____ | _____ |

**Participant Contact Details (please fill in below if you consent for a researcher to contact you):**

| | | | |
|---|---|---|---|
| **Address: (please print)** | _____ | | |
| | _____ | **Postcode:** | _____ |
| **Telephone:** | _____ | **Mobile:** | _____ |
| **Email address:** | _____ | | |

**For Clinician**: I have explained the DiReCT study to the above patient and he/ she has indicated which parts they consent to.

| Name of DAS Clinician: | Date: | Signature of Clinician: |
|---|---|---|
| _____ | _____ | _____ |

UNIVERSITY OF EXETER

Devon Partnership NHS
NHS Trust

*1 copy for participant, 1 copy for researcher, 1 copy for clinician*